JAN 2 4 2001

K003511

tyco / Healthcare / Ludlow

The Ludlow Company LP
Two Ludlow Park Drive
Chicopee, MA 01022

510(k) Summary

Manufacturer	The Ludlow Company LP Two Ludlow Park Drive Chicopee, MA 01022 Registration Number 9001764
Manufacturing Location	Ludlow Technical Products 15272 Jason Circle Huntington Beach, CA 92649 Registration Number 2025811
Telephone	(413) 593-6400
Contact Person	Kathleen M. Murphy Regulatory Affairs Manager Phone: (413)-593-6400 Fax: (413) 593-6114
Device Trade Name	Kendall-LTP Turner Save-A-Line
Common Name	Position Holder
Classification Name	Holder, Infant Position
Regulatory Reference	80 FRP
Predicate Device	Sentry Babyboard

The Ludlow Company LP
Two Ludlow Park Drive
Chicopee, MA 01022

Description The Turner Save-A-Line is a cloth covered foam substrate that is shaped such that it loops over the middle finger of the infant, across the palm, and wraps around the wrist of the infant.

Typical packaging configuration for the Turner Save-A-Line is one pair to a pouch, 50 pairs to a box, 100 pairs to a carton

Intended Use The Turner Save-A-Line is worn on the infant's hand and impedes the infant's ability to grasp components of and dislodge medical devices such as I.V. lines, chest tubes, feeding tubes, central lines, etc. The Turner Save-A-Line accomplishes this by supporting the palm to stabilize the hand.

Physical and Technical Comparison

Characteristic	Turner Save-A-Line	Sentry Babyboard
Body Material	Cloth covered Foam	Cloth covered Foam
Reusable	No	No
Application	Limb stabilization	Limb stabilization
Patient Population	Infant Patients	Infant Patients
Body Position Stabilized	Hand	Arm or Leg

Performance Summary FDA has not established special controls or performance standards for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2001

Ms. Kathleen M. Murphy
Regulatory Affairs Manager
The Ludlow Company, LP
Two Ludlow Park
Chicopee, Massachusetts 01022

Re: K003511
Trade Name: Kendall-LTP Turner Save-A-Line
Regulatory Class: I
Product Code: FRP
Dated: November 9, 2000
Received: November 14, 2000

Dear Ms. Murphy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003511

Device Name: Turner Save-A-Line

Indications for Use:

The Turner Save-A-Line is indicated for use on neonatal patients to stabilize the neonate's hand and to prevent the grasping and dislodging of I.V. Lines.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

Patricia Cuccia

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003511